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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 06005.00001)

RECEIVED
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In re Application of:)
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Simonson et al.)
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Serial No.: 10/061,036)
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)
Filed: January 30, 2002)
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)
For: Rapid Lateral Flow Assay for Determining)
Exposure to Mycobacterium Tuberculosis and)
Other Mycobacterium)

Examiner: (TBA)
Group Art
Unit: 1743

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-SB/08A. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent issued therefrom.

U.S. PATENT DOCUMENTS

<u>Patent Number</u>	<u>Inventor(s)</u>	<u>Publication Date</u>
4,268,434	Higerd et al.	05-19-81
4,458,014	Ebersole	07-03-84
4,639,419	Olson et al.	01-27-87

<u>Patent Number</u>	<u>Inventor(s)</u>	<u>Publication Date</u>
4,866,167	Chen et al.	09-12-89
4,965,192	Maes	10-23-90
5,830,410	Thieme et al.	11-03-98
5,922,614	Cesarczyk	07-13-99

PUBLICATION DOCUMENTS:

1. Wilkinson R.J., Haslov, K., Rappuoli, R., Giovannoni, F., Narayanan, P.R., Desai, C.R., Vordermeier, H.M., Paulsen, J., Pasvol, G., Ivanyi, J., and Singh, M. Evaluation of the recombinant 38-kilodalton antigen of *Mycobacterium tuberculosis* as a potential immunodiagnostic reagent. *J. Clin. Microbiol.* 35(3): 553-7. Mar 1997.
2. Maekura, R., Nakagawa, M., Nakamura, Y., Hiraga, T., Yamamura, Y., Ito, M., Ueda, E., Yano, S., He, H., Oka, S., et al. Clinical evaluation of rapid serodiagnosis of pulmonary tuberculosis by ELISA with cord factor (trehalose-6, 6'-dimycolate) as antigen purified from *Mycobacterium tuberculosis*. *Am. Rev. Respir. Dis.* 148:997-1001. Oct, 1993.
3. Young, D., Kent, L., Rees, A., Lamb, J., and Ivanyi, J. Immunological activity of a 38-kilodalton protein purified from *Mycobacterium tuberculosis*. *Infect. Immun.* 54(1): 177-83. Oct, 1986.
4. Singh, M., Andersen, A.B., McCarthy, J.E., Rohde, M., Schutte, H., Sanders, E., and Timmis, K.N. The *Mycobacterium tuberculosis* 38-kDa antigen: overproduction in *Escherichia coli*, purification and characterization. *Gene* 117(1): 53-60. Aug. 1992.

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6. Bassey, E.O.E., Catty, D., Kumararatne, D.S., and Raykundalia, C. Candidate antigens for improved serodiagnosis of tuberculosis. *Tubercle Lung Dis.* 77:136-145. 1996.
7. Kadival, G.V., Chaparas, S.D., and Hussong, D. Characterization of serologic and cell-mediated reactivity of a 38-kDa antigen isolated from *Mycobacterium tuberculosis*. *J. Immunol.* 139(7): 2447-51. Oct, 1987.
8. Fujiwara, N., Pan, J., Enomoto, K., Terano, Y., Honda, T., and Yano, I. Production and partial characterization of anti-cord factor (trehalose- 6,6'-dimycolate) IgG antibody in rabbits recognizing mycolic acid subclasses of *Mycobacterium tuberculosis* or *Mycobacterium avium*. *FEMS Immunol. Med. Microbiol.* 24(2): 141-9. Jun, 1999.
9. He, H., Oka, S., Han, Y.K., Yamamura, Y., Kusunose, E., Kusunose, M., and Yano, I. Rapid serodiagnosis of human mycobacteriosis by ELISA using cord factor (trehalose-6, 6'-dimycolate) purified from *Mycobacterium tuberculosis* as antigen. *FEMS Microbiol. Immunol.* 3(4): 201-4. Aug, 1991.
10. Enomoto, K., Oka, S., Fujiwara, N., Okamoto, T., Okuda, Y., Maekura, R., Kuroki, T., and Yano, I. Rapid serodiagnosis of *Mycobacterium avium-intracellulare* complex infection by ELISA with cord factor (trehalose 6, 6'-dimycolate), and serotyping using the glycopeptidolipid antigen. *Microbiol. Immunol.* 42(10): 689-96. 1998.
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oligomeric structure *in vitro* to suppress thermal aggregation. *J. Biol. Chem.* 271:7218-7223. 1996.

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The present Disclosure Statement is being submitted in compliance with 37 C.F.R. 1.56 as an Examiner might consider the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of such documents is not to be construed as an admission that such documents are necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner in the normal course of examination, will make an independent search and will determine the best prior art consistent, and in the course of such search, will review for relevance the documents cited on the attached form even if not initialed.

The accompanying Information Disclosure Statement is being filed within three months of the U.S. filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required.

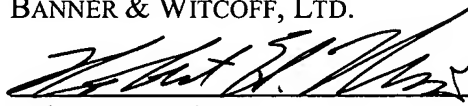
Early and favorable consideration is earnestly solicited.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: June 14, 2002

By:


Robert H. Resis
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